

**IN THE UNITED STATES DISTRICT COURT
FOR THE MIDDLE DISTRICT OF NORTH CAROLINA**

MAXWELL KADEL, et al.,

Plaintiffs,

v.

DALE FOLWELL, et al.,

Defendants.

No. 1:19-cv-00272-LCB-LPA

**REPLY IN SUPPORT OF PLAINTIFFS' MOTIONS TO EXCLUDE EXPERT
TESTIMONY OF DR. PETER ROBIE (ECF NO. 202), DR. PAUL W. HRUZ (ECF
NO. 204), DR. PAUL R. MCHUGH (ECF NO. 206), DR. PATRICK W. LAPPERT
(ECF NO. 208), AND DR. STEPHEN B. LEVINE (ECF NO. 212)**

Defendants willfully ignore the Fourth Circuit's most recent and relevant reaffirmance of "the indispensable nature of district courts' Rule 702 gatekeeping function in all cases in which expert testimony is challenged." *Sardis v. Overhead Door Corp.*, 10 F.4th 268, 284 (4th Cir. 2021). The Court should disregard Defendants' plea for lax gatekeeping and instead should rigorously examine the challenged experts' qualifications and the relevance and reliability of their testimony.

ARGUMENT

"The proponent of expert testimony has the burden of establishing its admissibility by a preponderance of proof." *Smith v. Wyeth-Ayerst Lab's Co.*, 278 F.Supp.2d 684, 691 (W.D.N.C. 2003). Defendants fail to meet this burden, however, even after specific challenges regarding each experts' qualifications and opinions. Defendants' failure to address specific arguments amounts to waiver, which is reason enough to exclude those opinions. *See, e.g., Stenlund v. Marriott Int'l, Inc.*, 172 F.Supp.3d 874, 887 (D. Md. 2016) ("In failing to respond to this argument [in defendant's motion], Plaintiff concedes the point.").

I. DEFENDANTS' EXPERTS ARE NOT QUALIFIED TO OPINE ON THE DIAGNOSIS AND TREATMENT OF GENDER DYSPHORIA.

There is no such thing as a jack-of-all-trades expert. Accordingly, "any expert, including physicians, must have the specialized knowledge or skill *in the specific area in which the testimony is proffered.*" *Smith*, 278 F.Supp.2d at 698 (emphasis added).

"Experience in a particular field is not enough to qualify an expert; *the expert must have experience with the issue before the court.*" *Harvey v. Novartis Pharm. Corp.*, 895

F.Supp.2d 1206, 1209 (N.D. Ala. 2012) (emphasis added); *see also, e.g., Zellers v. NexTech Ne., LLC*, 533 F.App’x 192, 197 (4th Cir. 2013) (neurologist not qualified to testify as an expert about toxicology because “she lacks specific training in th[at] field”); *Hubbard v. Rite Aid Corp.*, 433 F.Supp.2d 1150, 1161 (S.D. Cal. 2006) (dermatologist not qualified as expert in disability). Courts thus routinely recognize that an expert in a particular subspecialty is not *ipso facto* an expert in every other subspecialty within the same field—let alone in an entirely different field. *See, e.g., Elegant Massage, LLC v. State Farm Mut. Auto. Ins. Co.*, 2022 WL 433006, at *9 (E.D. Va. Feb. 11, 2022) (“the Fourth Circuit has recognized that experience and expertise in one area does not automatically qualify someone as an expert in another similar area”); *Maldonado v. Apple, Inc.*, 2021 WL 1947512, at *17 (N.D. Cal. May 14, 2021) (chemical engineer not qualified to opine about “reliability engineering,” because “slapping the label ‘engineering’ on an expert or opinion is insufficient to show expertise across that expansive field”); *Shreve v. Sears, Roebuck & Co.*, 166 F.Supp.2d 378, 392 (D. Md. 2001) (“an expert who is a mechanical engineer is not necessarily qualified to testify as an expert on any issue within the vast field of mechanical engineering”).

Defendants concede—as they must—that their experts cannot qualify based on scientific research and peer-reviewed writing in this area. Instead, Defendants argue that their experts are qualified based on their generalized knowledge, skill, and education in their fields of medicine. That is not enough, however, and Defendants cite no authority for their proposition that any physician may testify about gender dysphoria and its treatment

even if they have no specialized training, research experience, clinical experience, or peer-reviewed publications in the area.

Finally, Defendants conflate and misrepresent Plaintiffs' arguments regarding their experts' "unfamiliarity or disagreement with the ... [WPATH] standards of care." Dkt. 215 at 16. If a challenged expert is unfamiliar with the WPATH Standards of Care, that calls into question both the expert's qualifications *and reliability*. Separately, a challenged expert's disagreement with what is otherwise the recognized medical and scientific consensus calls into question their *reliability* because general acceptance in the relevant scientific community is an important element of reliability. *See Nease v. Ford Motor Co.*, 848 F.3d 219, 229 (4th Cir. 2017).

A. Dr. Robie

Defendants concede that Dr. Robie will not opine regarding "the efficacy of gender dysphoria treatment," Dkt. 215 at 15—not surprising, since Dr. Robie admitted he lacks experience with this area. Dkt. 202 at 8. Instead, Defendants say that Dr. Robie will testify to the medical knowledge he shared with other Board members. Dkt. 215 at 15. But that is a role of a fact witness, not an expert. Moreover, as he stated in his deposition, the knowledge he shared relates to coverage of continuous glucose monitors for diabetic patients, biological agents for cancer treatment, and COVID management, care, and status. Dkt. 203-1 at 23:11–25:12; 31:19–32:14. These issues are irrelevant to this dispute, and there is no need for purported expert testimony on them.

B. Dr. Hruz

Defendants argue Dr. Hruz is qualified to testify as an expert in this case because he has purportedly “extensively studied the scientific literature related to the incidence, potential etiology, and treatment of gender dysphoria.” Dkt. 215 at 14; *but see* Dkt. 205 at 20-22 (noting misrepresentations about the nature of his study in the area). However, Dr. Hruz has no clinical, research, or scientific publication experience in this area. And the fact that Dr. Hruz has “read in the area” and “holds an opinion on the topic” “is not enough” to make him an expert on this topic. *United States v. Jacques*, 784 F.Supp.2d 59, 62 (D. Mass. 2011); *see also Zellers*, 533 F.App’x at 197 (neurologist not an expert on toxicology because she reviewed scientific literature on toxicology).

C. Dr. McHugh

In arguing that Dr. McHugh is qualified, Defendants do nothing other than recite his credentials. But “a proffered expert’s professional qualifications are insufficient to support his testimony; he must also have sufficient specialized knowledge to assist the jurors in deciding the particular issues in the case.” *Belk, Inc. v. Meyer Corp., U.S.*, 679 F.3d 146, 162 (4th Cir. 2012) (cleaned up). Here, Dr. McHugh has no clinical, research, or scientific publication experience regarding the diagnosis or treatment of gender dysphoria and is therefore unqualified to testify as to those issues. Dkt. 207 at 5-9.

D. Dr. Lappert

Defendants do not contend that Dr. Lappert is qualified to opine on topics other than plastic surgery (like endocrinology, psychiatry, mental health conditions, and development

of treatment guidelines)—again not surprising, since he conceded he is not an expert in those areas. Dkt. 209 at 9-10, 15-16; *e.g.*, *Scott v. Mid-Atlantic Cable Installation, LLC*, 2006 WL 2079373, at *3 (E.D. Va. July 25, 2006); *Nunez v. Coloplast Corp.*, 2020 WL 2315077, at *5-6 (S.D. Fla. May 11, 2020).

As to surgery, Defendants argue Dr. Lappert is qualified to testify based on his “personal experience with the surgical procedures performed as part of sex reassignment surgery,” although not “for treatment of gender dysphoria.” Dkt. 215 at 14-15. But that is not enough. Defendants do not explain how Dr. Lappert’s experience performing these procedures for *other conditions* qualifies him to opine on the efficacy of these procedures to treat *gender dysphoria*. See *Harvey*, 895 F.Supp.2d at 1210–11; *Thomas v. Novartis Pharms. Corp.*, 443 F.App’x 58, 63 (6th Cir. 2011) (finding experienced maxillofacial surgeon who had treated patients with osteonecrosis of the jaw unqualified to opine on the causation of osteonecrosis of the jaw).

Finally, Defendants fail to respond to Plaintiffs’ argument regarding the Code of Ethics of the American Society of Plastic Surgeons requiring plastic surgeons to have “performed the specific procedure in question within three (3) years of the date of being retained as an expert witness,” which Dr. Lappert has not. Dkt. 209 at 8.

E. Dr. Levine

Plaintiffs have established that Dr. Levine is not qualified to offer opinions about the treatment of prepubescent transgender children. Dkt. 213 at 20-22. In response,

Defendants only recite Dr. Levine's credentials. But again, credentials alone are "insufficient to support [an expert's] testimony." *Belk, Inc.*, 679 F.3d at 162.

II. THE CHALLENGED EXPERTS' OPINIONS ARE IRRELEVANT AND UNRELIABLE.

"[T]he party seeking the admission of expert testimony must come forward with evidence from which the court can determine that the proffered testimony is ... reliable and relevant." *In re Smith & Nephew Birmingham Hip Resurfacing (BHR) Hip Implant Prod. Liab. Litig.*, 2021 WL 781682, at *2 (D. Md. Mar. 1, 2021). Defendants fail to meet this burden.

A. Defendants do not refute that many of the challenged experts' opinions are irrelevant.

Relevancy "is a precondition to admissibility." *Sardis*, 10 F.4th at 282 (cleaned up). "The test for relevance, or fit, considers whether expert testimony proffered in the case is sufficiently tied to the facts of the case that it will aid the jury in resolving a factual dispute." *Viva Healthcare Packaging USA Inc. v. CTL Packaging USA Inc.*, 197 F.Supp.3d 837, 846 (W.D.N.C. 2016) (cleaned up).

In asserting their experts' testimony is relevant, Defendants set up a strawman. Defendants claim that "medical uncertainty" exists around the treatment of gender dysphoria, based on a statement made by Treasurer Folwell. Dkt. 215 at 17-19. They fail to mention, however, that Treasurer Folwell's belief comes from Dr. Robie, who Defendants concede is not qualified to opine on the treatment of gender dysphoria. Dkt. 180 (Ex. 11 (Folwell Deposition) at 170:8-171:8 ("Q: ... your belief that there was medical

uncertainty of this elective procedure was based on conversation you had with Dr. Robie? A: Generally speaking.”)). The Plan cannot claim “uncertainty” exists and shoehorn expert testimony based on the speculation and conjecture of an individual who is not even qualified to opine on the subject.

Further, Defendants do not rebut Plaintiffs’ challenges to the relevancy of certain opinions by their experts. Accordingly, the Court should exclude opinions related to

1. desistence (Dkt. 205 at 9-10; 207 at 10-11; 209 at 18-19);
2. supposed controversies in other countries (Dkt. 205 at 10-11);
3. hypotheses about the causation of gender dysphoria (Dkt. 205 at 11; 207 at 12; 209 at 18-19);
4. the validity and reliability of the DSM, which does not set forth treatment (Dkt. 207 at 11);
5. Dr. Levine’s opinions about the etiology and immutability of sex (Dkt. 213 at 8-9); and
6. Dr. Robie’s opinions about the supposed need for physicians to know the chromosomal makeup of their patients (Dkt. 203 at 13-14).

B. The challenged experts’ opinions are unreliable.

Expert testimony should only be admitted if it is reliable and “proffered evidence that has a greater potential to mislead than to enlighten should be excluded.” *In re Lipitor (Atorvastatin Calcium) Mktg., Sales Pracs. & Prods. Liab. Litig. (No II) MDL 2502*, 892 F.3d 624, 632 (4th Cir. 2018) (cleaned up). Moreover, “where a party seeks to qualify a

witness as an expert based upon experience, the district court must require the experiential witness to explain how his experience leads to the conclusion reached, why his experience is a sufficient basis for the opinion, and how his experience is reliably applied to the facts.” *Jackson v. United States*, 2010 WL 2228378, at *6 (D.S.C. May 28, 2010) (cleaned up).

Here, again, Defendants fail to meet their burden and have not contended with many of Plaintiffs’ arguments regarding reliability. Where Defendants do not address a particular argument, they should be deemed to have conceded the point.

1. Dr. Robie

Defendants now contend Dr. Robie’s opinions are limited to (1) medical knowledge he shared with other Board members;¹ (2) the diagnostic process primary care physicians follow; and (3) the importance of accurate information about a patient’s chromosomal sex during that process. Dkt. 215 at 34-35; Dkt. 215-5.²

But Dr. Robie does not inquire about his patients’ chromosomal makeup normally, Dkt. 203 at 13-14, and therefore cannot explain how such knowledge is important to the diagnostic process. Moreover, he only formed this opinion in 2019 in connection with this litigation. Accordingly, his opinion on this should be excluded as unreliable. *See Kiessling v. Kiawah Island Inn Co. LLC*, 2019 WL 331176, at *8 (D.S.C. Jan. 25, 2019).

¹ As noted above, to the extent Defendants say that Dr. Robie will testify to the medical knowledge he shared with other Board members, that is the role of a *fact* witness, not an expert.

² The Court should exclude any other expert opinions by Dr. Robie beyond these three, including those regarding costs (*see* Dkt. 203 at 15-17).

2. Dr. Hruz

Defendants do not refute that all of Dr. Hruz's opinions are based on hypotheses and not *facts*. Dkt. 205 at 11-13. "Speculation, guesswork and conjecture are not acceptable substitutes for facts and data, and an opinion based on speculation is not founded on reliable methodology." *Samuel v. Ford Motor Co.*, 112 F.Supp.2d 460, 470 n.11 (D. Md. 2000). And because "[a]n expert's opinion should be excluded when it is based on assumptions which are speculative and are not supported by the record," *Tyger Const. Co. Inc. v. Pensacola Const. Co.*, 29 F.3d 137, 142 (4th Cir. 1994), all of Dr. Hruz's opinions should be excluded.

Defendants also fail to rebut Plaintiffs' arguments about the misleading nature of some of Dr. Hruz's opinions. Dkt. 205 at 13-17. Defendants portray these arguments as mere disagreements, but there are no "alternative facts" in court. *See Old White Charities, Inc. v. Bankers Ins., LLC*, 2018 WL 8622359, at *6 n.10 (S.D.W. Va. Aug. 28, 2018). "Facts must be facts and truth must be truth." *Id.* at *6. Dr. Hruz is untruthful when he says gender-affirming care has not been accepted by relevant scientific communities, or when he says no medical care is provided to adolescents and adults with gender dysphoria under the "watchful waiting" model. Dkt. 205 at 13-14, 15. His opinions are more likely to mislead than to enlighten.

In addition, Dr. Hruz has conducted no scientific research or study with regards to gender dysphoria, rather he has read some articles and talked with other professionals. *Id.* at 6-7. But not only does he misrepresent the nature of his conversations, *see id.* at 20-22,

conversations with others health care professionals do not make him an expert. *See Jackson*, 2010 WL 2228378, at *7.

Finally, Defendants do not address Plaintiffs' argument that Dr. Hruz's testimony is unreliable because it is permeated by unscientific views and bias. Dkt. 205 at 19-23.

3. Dr. McHugh

Defendants' assertion that Plaintiffs' challenge opinions by Dr. McHugh not in his report strains credulity. The desistence opinions that Dr. McHugh offered at his deposition are rooted in his report. *See* Dkt. 207-4 at 14. Likewise, Dr. McHugh's opinions about reparative therapy are connected to his opinions that gender-affirming care is harmful and/or experimental. His belief in reparative therapy (widely considered harmful and unethical) as the proper mode of treatment for gender dysphoria underscores the unreliability of his opinions. Defendants also do not refute that the foundation of Dr. McHugh's opinions is that transgender people are supposedly "disordered" because they suffer from a "disorder of assumption" or "overvalued idea." Dkt. 207 at 13-14.

Defendants argue that Plaintiffs deem Dr. McHugh's views unreliable solely because he disagrees with the WPATH Standards of Care. Not true. Dr. McHugh's opinions conflict with those of *every* major medical or health organization in the United States. *Id.* at 14-17. This includes the U.S. Department of Health and Human Services ("HHS"), which just last week, proclaimed that, "[HHS] and all leading national medical and pediatric associations confirm that providing gender-affirming medical care is in the best interest of children and youth who need it." Ex. A.

Defendants also do not refute that Dr. McHugh's opinions are based on speculation and untested theories, Dkt. 207 at 17-18, and thus should be excluded because "speculation is unreliable evidence and is inadmissible." *Dunn v. Sandoz Pharms. Corp.*, 275 F.Supp.2d 672, 684 (M.D.N.C. 2003). Nor do Defendants refute that Dr. McHugh's opinions about the provision of care in other countries are both unreliable and misleading. Dkt. 207 at 18.

Defendants argue the Court should permit Dr. McHugh's opinions about the DSM, but aside from being irrelevant, those opinions are highly misleading, and Dr. McHugh's proposed alternative to the DSM "has been able to attract only minimal support within the community." Dkt. 207 at 19-20.

Finally, Defendants do not even attempt to negate that Dr. McHugh's opinions are so tainted by bias and prejudice that they are unreliable. *Id.* at 22-24.

4. Dr. Lappert

Ignoring their burden, Defendants do not respond to Plaintiffs' arguments that Dr. Lappert's non-surgery-related opinions are unreliable. Dkt. 207 at 9-10, 15-20. Whatever the reason for Defendants' failure to respond, they have not carried their burden to demonstrate that these opinions satisfy Rule 702.

Dr. Lappert's opinions on risks of surgical procedures are also unreliable. In particular, he opines about the supposed risks of these procedures when used to treat gender dysphoria. But that is a specific application of these procedures to a particular population with which Dr. Lappert admittedly has no first-hand experience whatsoever, and for which

he therefore has no basis to offer expert testimony. *See, e.g., SDM Software, Inc. v. EMove, Inc.*, 945 F.Supp.2d 628, 639 (E.D.N.C. 2013).

5. Dr. Levine

Defendants summarize some of what Dr. Levine will say but do not explain “how his experience leads to the conclusion reached” or “how his experience is reliably applied to the facts.” *Jackson*, 2010 WL 2228378, at *6 (cleaned up). Dr. Levine’s opinions are not relevant and reliable just because Defendants deem it so. Defendants cannot explain how Dr. Levine’s testimony will enlighten the factfinder, because it will not. And here, where Dr. Levine testified that he follows and applies the WPATH Standards of Care in his own practice, Dkt. 213 at 6-8, 12-13, his testimony against coverage of this care has a greater potential to mislead than to enlighten.

Ultimately, Defendants argue that Dr. Levine’s testimony about a purported lack of studies is based on his review of scientific literature and provides a basis for a factfinder to conclude the Exclusion is justified. But what Dr. Levine and Defendants fail to do explain how the alleged lack of long-term studies somehow proves that gender-affirming treatment is not medically necessary and effective, particularly given the multitude of cross-sectional, observational, and longitudinal studies demonstrating the efficacy of such treatment.³

³ The Court should disregard Defendants’ arguments about what certain studies show. Not only do Defendants misrepresent those studies (*e.g.*, Dkt. 207 at 18 n.5; 213 at 13-14), but legal argument from Defendants’ counsel is not expert testimony.

CONCLUSION

It is Defendants' burden to prove that the challenged experts are qualified and that their opinions are relevant and reliable; they have failed to do so. Defendants do not explain how their experts' experience leads to their conclusions, why their experience is a sufficient basis for their opinions, and how their experience is reliably applied to the facts of this case. To the contrary, the challenged experts' opinions are based on conjecture.

The Court should grant Plaintiffs' motions to exclude expert testimony.

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CERTIFICATE OF COMPLIANCE

I hereby certify that the foregoing brief is in compliance with Local Rule 7.3(d)(1) because the body of this brief, including headings and footnotes, does not exceed 3,125 words as indicated by Microsoft Word, the program used to prepare this document.

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CERTIFICATE OF SERVICE

I certify that the foregoing document was filed electronically with the Clerk of Court using the CM/ECF system which will send notification of such filing to all registered users.

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